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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/212,367 12/15/98 BAUNOCH

D 98-714

020306 IM22/0227  
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EXAMINER

BEISNER, W  
ART UNIT  PAPER NUMBER

1744  
**DATE MAILED:**

02/27/01 *JS*

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/212,367	BAUNOCH ET AL.
	Examiner	Art Unit
	William H. Beisner	1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-6 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-6 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- |  |  |
|--|--|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                          | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>11</u> . | 20) <input type="checkbox"/> Other: _____.                                   |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The information disclosure statement filed 20 July 2000 has been lined through because the references listed on this PTO-1449 have already been considered and made of record. See Paper Nos. 8 and 10.

### ***Drawings***

2. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed. See PTO-948 form attached to Paper No.7. The Examiner recognizes Applicants' intention to file corrected drawings upon notification of allowable subject matter.

### ***Specification***

3. The description portion of this application contains a computer program listing consisting of more than ten (10) pages. In accordance with 37 CFR 1.96(c), a computer program listing printout of more than ten pages must be submitted as a "microfiche appendix" conforming to the standards set forth in 37 CFR 1.96(c)(2) and must be appropriately referenced in the specification (see 37 CFR 1.77(a)(6)). Accordingly, applicant is required to cancel the computer program listing appearing in the specification on pages 24-42, file a "microfiche appendix" in compliance with 37 CFR 1.96(c) and insert an appropriate reference to the newly added "microfiche appendix" at

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the beginning of the specification. The Examiner recognizes Applicants' intention to file corrected drawings upon notification of allowable subject matter.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102((e), f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kinney et al.(US 4,001,460) in view of either Mathiesen et al.(WO 95/17657) or Didenko et al.(US 6,013,438).

The reference of Kinney et al. discloses an automated system for processing a tissue sample. The system includes a processing chamber, 12, for holding a sample; means for regulating the flow of fluid, 39 and 60; at least one container of clearant agent, 7, 8 and 9; at least one container of dehydrant agent, 2-6; at least one container of an aqueous fluid, 1; and a control device, 100.

While the reference of Kinney et al. includes all of the instantly claimed structures of the device, the reference differs because it fails to disclose that the control device regulates the flow of fluid in the claimed sequential flow as recited in the claims.

The references of Mathiesen et al. (See page 8) and Didenko et al.(See column 4, line 66 to column 5, line10) both disclose methods of fixing specimens in paraffin which includes a deparaffinizing step so as to remove the paraffin and further process the specimen with stain and/or further reagents. Both of these deparaffination procedures include sequential steps of contacting the specimen with clearant, dehydrant and water.

In view of either of these teachings, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of Kinney et al. so as to provide both the disclosed fixing procedure and the deparaffination steps disclosed by the secondary references for the known and

expected result automating the deparaffination steps with an automated system recognized in the art.

With respect to claim 2, the reference of Kinney et al. discloses the use of a rotary valve. In view of the suggestion discussed above, it would have been obvious to one of ordinary skill in the art to modify the rotary valve device and/or provide additional reservoirs of agents so as to provide the sequential flow of agents required to perform the conventional deparaffination steps.

With respect to claim 3, the device of Kinney et al. already includes separately provided paraffin reservoirs which are separately controlled for flow with respect to the other treating agents.

With respect to claim 4, it would have been obvious to one of ordinary skill in the art to treat a specimen after the deparaffination steps with conventional fixation steps for the known and expected result of fixing the specimen for use at another time and/or for storage.

Claims 5 and 6 require the use of purge clearant and purge dehydrant. The reference of Kinney et al. discloses the use of purge clearant, 9, and purge dehydrant, 10, in the system. In view of this disclosure, it would have been obvious to one of ordinary skill in the art to determine the optimum manner in which to purge the system prior to contacting the specimen with the treating agents.

***Response to Arguments***

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8. Applicant's arguments filed 28 Dec. 2000 have been fully considered but they are not persuasive.

Applicants argue that the instant invention is not obvious due to a long-felt need for the invention.

In response, first the Examiner would like to point out that both the prior art and applicants' own specification recognize that manual reprocessing of paraffin embedded tissue samples is known in the art. As a result, in view of the automated system disclosed by the reference of Kinney et al. the Examiner maintains that automation of the reprocessing procedure would have been obvious in view of the structure disclosed by the reference of Kinney et al. It is well established that "broadly providing an automatic or mechanical means to replace a manual activity which accomplished that same result is not sufficient to distinguish over the prior art". See *In re Venner*, 120 USPQ 193 (CCPA 1958).

Furthermore, Applicants' traversal of the obviousness rejection of record in view of the secondary consideration of "long-felt need" is not found to be persuasive in the absence of the submission of objective evidence to support this secondary consideration of nonobviousness. Establishing long-felt need requires objective evidence that an art recognized problem existed in the art for a long period of time without solution. See MPEP 716.04.

### ***Conclusion***

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9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 703-308-4006. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:40am to 4:10pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Warden can be reached on 703-308-2920. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3599 for regular communications and 703-305-7718 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

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William H. Beisner  
Primary Examiner  
Art Unit 1744

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February 23, 2001